

July 2006

Please send comments and feedback on this document to: Tony Richardson, lmr7@cdc.gov
Thank you.





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Disclaimer

This document's purpose is to provide a uniform understanding of the Centers for Disease Control and Prevention (CDC) vaccine contract procurement process. The intent is to communicate the information to immunization grantees and CDC's National Center for Immunization and Respiratory Diseases (NCIRD) personnel and to promote the importance and awareness of the vaccine contracts process. The information provided is for general reference only. Should any discrepancy arise between an NCIRD policy and this document, the wording in the NCIRD policy shall apply. While this document provides an explanation for the CDC vaccine contracts, it is not intended to replace the actual contracts in content. Each contract should be reviewed for specific directions.

NCIRD's commitment is to make the information in this document accurate, complete and current. As regulations, policies, protocols and procedures are altered on a regular basis, information may be updated or changed without notice. We will periodically update this document to remove outdated information. The last revision date of the information will be provided. Users are advised to consult the Vaccine Supply and Assurance Branch at NCIRD to determine if the posted information is still valid. CDC assumes no liability for use or misuse of any information contained within this document.

Foreword

An NCIRD Vaccine Contracts Workgroup was established from staff of the Program Operations Branch and Vaccine Supply and Assurance Branch at NCIRD.

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The objectives of the workgroup were:

- To identify and clarify useful information related to CDC/NCIRD vaccine contracts process and,
- To establish a reference point, in the form of a guide, that expands on current guidance, provides background information and establishes a framework to support appropriate policy and decisions when purchasing and using CDC/NCIRD federal contracted vaccines

User's Guide for Vaccine Contracts

The *User's Guide for Vaccine Contracts* includes requirements for all contracted vaccine procurement activities (Pediatric/VFC, Adult & Influenza). The guide is also explicitly aimed at summarizing generally accepted practices regarding NCIRD's federal vaccine contracts.

Acknowledgements

The National Center for Immunization and Respiratory Diseases relies on the hard work and dedication of the 64 immunization grantees and their local programs. Without their commitment, we would not be able to successfully protect the people from vaccine preventable disease. In addition, appreciation goes to CDC's Procurement and Grants Office (PGO), the Centers for Medicare and Medicaid Services (CMS), Health Resources and Services Administration (HRSA) and its Division of Vaccine Injury Compensation and Maternal and Child Health (MCH) branch for helping us to fulfill our mission. We thank them all.

Letter from the Director

July 10, 2006

Dear Immunization Program Managers:

The federal government began to purchase polio and measles vaccines in 1966. The federally funded vaccine program expanded substantially with the passage of the Vaccines for Children (VFC) legislation in 1993. Today, the federal government, through the Centers for Disease Control and Prevention (CDC), is the single largest purchaser of vaccines in the United States. The federal vaccine programs allow states, local health departments and other providers to offer vaccines at no cost to children who meet certain federal eligibility requirements.

The *User's Guide for Vaccine Contracts* describes the purpose, process, and regulations of federal government contracts for vaccine purchased through CDC. This document outlines CDC's process for developing the contracts, including roles of the National Center for Immunization and Respiratory Diseases (NCIRD), the Procurement and Grants Office (PGO) and the Financial Management Office (FMO). The roles and responsibilities of the vaccine manufacturers and the state and local jurisdictions are also discussed. In addition, the *User's Guide for Vaccine Contracts* contains a Frequently Asked Questions (FAQ) section to answer the most frequently asked questions about federal vaccine contracts.

We hope that you find this document useful.

Sincerely,

Lance E. Rodewald, M.D.

Director, Immunization Services Division

National Center for Immunization and Respiratory

Diseases

Centers for Disease Control and Prevention

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INTRODUCTION

What is a CDC Vaccine Contract?

A CDC vaccine contract is a formal written agreement executed between the Centers for Disease Control and Prevention (CDC) and a vaccine manufacturer or supplier for the procurement of contractual vaccine services and commodities.

Purpose of CDC Vaccine Contracts

CDC has negotiated unified vaccine contracts since 1966. The purpose of these contracts is to secure a uniform price for vaccines for 64 state and local immunization programs¹ supported by federal, state and local funds. These contracts generally seek to secure a sufficient amount of vaccine to meet the needs of public health programs in the United States. Purchases through CDC contracts accounted for approximately 54 percent of all childhood vaccine used in the United States in 2004.

Why a Vaccine Contracts Guide?

In order to meet the needs of immunization programs, it is necessary to provide consistent guidance and information. The purpose of a *User's Guide for Vaccine Contracts* is to outline the process for establishing federal contracts for vaccine purchase and establish a reference point that defines expected practices for immunization programs. Currently, NCIRD has minimal written policies or guidelines that can be used to assist Section 317 and <a href=Vaccines for Children Program Project Officers, as well as immunization projects with day-to-day vaccine contract compliance and decision-making. With immunization programs conducting business in many different ways, NCIRD wants to clearly describe the vaccine contract and procurement process to ensure quality service delivery and contract compliance. To summarize, the *User's Guide for Vaccine Contracts* expands on current guidance, provides background information and establishes frameworks to support appropriate policy and decisions when purchasing and using CDC contracted vaccines.

Who We Think Will Use the Guide

Many immunization programs' personnel may not have had the opportunity to review vaccine ordering instructions and award letters from CDC's Procurement and Grants Office (PGO) (see appendix). This guide was developed with immunization program staff, project officers and field assignees of the Program Operations Branch (POB) in mind. It was also developed for those who are not familiar with CDC vaccine contracts. Readers should find the *User's Guide for Vaccine Contracts* a supplemental benefit to the following:

Ordering Instructions – Consolidated Pediatric/Vaccines For Children (VFC) Vaccine Contracts

Ordering Instructions – CDC Adult Vaccine Contracts

¹ Immunization Programs refers to the 64 grant recipients—50 states, 8 territories, 5 cities, and the District of Columbia.

Ordering Instructions – CDC Influenza Vaccine Contracts

What This Guide Is Not

The *User's Guide for Vaccine Contracts* is not designed to replace the Federal Acquisition Regulations (FAR), Health and Human Services Acquisition Regulations (HHSAR) or PGO rules. This guide does not preclude anyone from seeking further vaccine contract information and clarification from NCIRD.

CDC Vaccine Contracts Funding Sources

Vaccine on CDC contracts can be purchased by immunization programs using three funding sources. The first and largest source of money comes from the Vaccines for Children (VFC) program. VFC funds are available through an entitlement program established under the Omnibus Budget Reconciliation Act (OBRA) of 1993. Under the VFC program, children are eligible to receive vaccine at no cost if they are younger than 19 years of age. These children must: 1) be eligible for the Medicaid program, or; 2) have no health insurance, or; 3) be a Native American or Alaska Native, or; 4) have health insurance that does not cover childhood immunization and receive services at a federally qualified health center (FQHC) or rural health clinic. In 2004, as indicated in figure 1, this source of money accounted for approximately 74 percent of public sector vaccine purchased through CDC contracts (40,106,615 doses) and 40 percent of the total vaccine purchased in the United States.

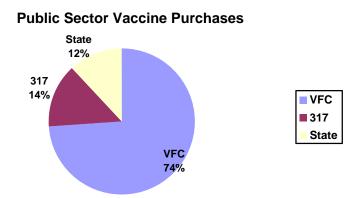
The second source of funding used to purchase vaccines from CDC contracts is referred to as Vaccine Purchase grants or Section 317 grant funds. Since 1963, CDC has provided grant support to help state and local health departments purchase safe and effective vaccines. The grant program aligns with Healthy People 2010 public health objectives as well as Department of Health and Human Services (DHHS) goals to increase access to healthcare and increase immunization coverage rates. Section 317 vaccine grants support the purchase of vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) through CDC's consolidated vaccine purchase contracts. These contracts are available to state and local immunization programs at reduced prices, saving states substantial amounts of money.² There are no restrictions on the use of vaccine purchased with Section 317 funding. Grantees are discouraged from using Section 317 funded vaccine to vaccinate fully insured people. Section 317 funds accounted for approximately 14 percent (7,921,950 doses) of the public vaccine purchased through CDC contracts in 2004.

The third source of funds used to purchase vaccine from a CDC contract is state or local funds. These are additional monies made available by the individual state legislatures or local governments to assist their immunization programs in immunizing the childhood or adult populations against selected vaccine preventable diseases. This source accounted for approximately 12 percent (6,673,740 doses) of the public vaccine purchased through CDC contracts in 2004.

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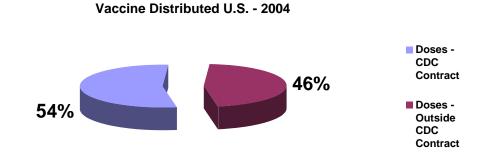
² CDC FY 2005 Performance Plan

Figure 1



CDC vaccine contracts generally seek to secure a sufficient amount of vaccine to meet the needs of public health programs in the United States. As illustrated in figure 2, purchases from CDC contracts accounted for approximately 54 percent of all childhood vaccine used in the United States in 2004.

Figure 2



Vaccine Management Business Improvement Project (VMBIP)

The VFC, 317 and state vaccine programs have produced significant improvements for public health over the past decade. However, NCIRD has recognized that vaccine management and accountability processes must be improved to ensure efficiency and success for immunization activities. In 2003, NCIRD established a team to conduct a comprehensive review of vaccine management activities at the federal, state and local levels in order to identify opportunities to improve efficiency, accountability and responsiveness to public health crises. This review led to the creation of a new initiative called the Vaccine Management Business Improvement Project (VMBIP). VMBIP's aim is to improve the processes of six components: Communications, Distribution, Fiscal Operations, Stockpile, Systems, and Vaccine Management and Accountability. Although this project is in its early stages, implementation and evaluation of the recommendations will be ongoing. Therefore, updates to this guide are expected throughout all phases of implementation.

CONTRACTS

NCIRD is responsible for coordinating the establishment of contracts for the ordering of vaccines in support of the VFC program under Section 1928 of the Social Security Act and purchases under Section 317(j) of the Public Health Service Act. Three groups of vaccine supply contracts are awarded on an annual basis: consolidated pediatric/VFC contracts, adult vaccine contracts and influenza vaccine contracts. Each group of contracts is discussed individually later in this section.

A. The Contracting Process in General

(1) Responsibilities

PGO is responsible for conducting the contracting process on behalf of NCIRD for all CDC vaccine supply contracts. This process includes issuing or posting presolicitation notices and solicitations, receiving and safeguarding proposals, coordinating the evaluation of proposals, leading negotiations, finalizing contract documents and administering the contracts including coordinating payment of invoices and final contract close out. The PGO Contracting Officer signs the contracts on behalf of the U.S. government and is the only CDC official with the authority to make changes to contract terms and conditions. The Contracting Officer designates an individual within NCIRD to serve as Project Officer during the contract performance period. The Project Officer is responsible for providing guidance in regard to the technical aspects of the contract, is the general focal point to address technical and logistical problems relating to the performance under the contract and serves as a liaison between the Contractor and other government agencies (federal and state).

(2) Type of Contracts

NCIRD's vaccine supply contracts are indefinite quantity/indefinite delivery type contracts that provide for the ordering of covered vaccines by immunization grantees on an as-needed basis. For each listed vaccine the contracts include a maximum estimated quantity (the total number of doses that can be ordered) and a guaranteed minimum quantity (the minimum number of doses that must be ordered). Because the vaccines purchased under CDC contracts are standard commercial products, acquisitions are conducted under streamlined procedures for the purchase of commercial items that are intended to closely resemble those of the commercial marketplace. CDC routinely awards multiple contracts for vaccine products that are produced by more than one manufacturer.

(3) The Solicitation and Award Process Several months before the contract start date, a pre-solicitation notice describing the vaccine contract requirements is developed and posted to the Federal Business Opportunities web site, (www.fedbizopps.gov) by PGO. This site is the single government point-of-entry for federal government procurement opportunities over \$25,000. Approximately two weeks later the solicitation document is posted to the same web site. The solicitation lists the vaccines required and includes terms and conditions of the contract. PGO receives proposals in response to the solicitation and forwards them to NCIRD for review and evaluation. Issues for discussion during negotiations are developed jointly by NCIRD and PGO. Negotiations are usually conducted via telephone conference calls with each company that submits a proposal. Final proposal revisions addressing the issues discussed are received and evaluated by NCIRD and PGO. Contracts are created and signed first by the contractor and then by the government. Immunization grantees are then notified of new contracts and prices.

(4) Terms, Conditions and Special Provisions (applicable to all contracts):

Set forth below are some pertinent contract terms and conditions and special provisions related to all NCIRD vaccine contracts (pediatric/VFC, adult and influenza contracts):

a. Minimum Order Size:

Each vaccine is subject to a minimum order size, i.e. the fewest number of doses that may be ordered for delivery to a single destination. This minimum order size varies by vaccine.

b. Federal Excise Tax:

Routinely recommended vaccines for children in the United States are subject to a federal excise tax of \$0.75 per dose, per antigen. For example, federal excise tax for a combination vaccine such as DTaP is \$2.25 per dose or \$0.75 per component or antigen. The taxes collected directly support the National Vaccine Injury Compensation Program (VICP), which provides a system of no-fault compensation for certain individuals who have been injured by VICP covered vaccines. Vaccine manufacturers are responsible for collection of the excise taxes and subsequent payment to the VICP. Immunization grantees should request federal excise tax credit for outdated or unusable vaccine. Policies and procedures for returning vaccine and requesting credit for federal excise tax can be found on the NCIRD web site.

c. Return Privileges:

All CDC vaccine contracts include a stipulation that vaccine is only returnable if the vaccine does not conform to specifications set forth in the contract. Therefore, vaccines purchased under CDC's contracts are not returnable for credit, reimbursement or exchange unless the vaccine received from the manufacturer did not meet contract requirements (i.e. expiration date or

appropriate packaging). In these cases, vaccine purchased under the CDC contracts is returnable for credit or product exchange only. The contract stipulation on vaccine returns does not apply to the return of vaccine for excise tax credit. All immunization programs should return unusable vaccine to the manufacturers for federal excise tax credit.

d. Payment Terms:

The government is required to pay all invoices not later than 30 calendar days after receipt of a proper invoice by the ordering or payment office. The Prompt Payment Act (Public Law 97-177) includes provisions for the payment of interest on invoices not paid within the 30 day period. This requirement for prompt payment applies to all vaccine orders, regardless of funding source.

B. Consolidated Pediatric/VFC Vaccine Contracts

(1) Contract Period of Performance:

CDC pediatric/VFC vaccine contracts begin on April 1 of each year (or date of award if the contracts are awarded after April 1) and end on March 31 of the following year. Contracts can be modified to include newly licensed/ACIP recommended vaccines as well as ACIP amendments to existing VFC resolutions.

(2) Vaccines Covered:

CDC attempts to negotiate vaccine contracts for all <u>ACIP recommended</u> <u>childhood vaccines</u>.

(3) Shelf Life:

CDC's pediatric/VFC vaccine contracts indicate a specified shelf life that all vaccines must have remaining upon delivery by the manufacturer to the designated recipient (i.e., state depot or private distributor). This is usually, at least, 12 months.

(4) Vaccine Ordering:

Immunization programs may purchase vaccines from any of the available consolidated pediatric/VFC vaccine contracts using federal VFC funds, federal 317 grant funds or their own state/local funds. Immunization grantees use the Vaccine Management Software (VACMAN) application to order vaccine from the available contracts. Orders submitted through VACMAN are evaluated and approved by NCIRD and forwarded to the contractors for fulfillment.

(5) Time of Delivery:

CDC's vaccine contracts stipulate that vaccines purchased from CDC consolidated pediatric/VFC vaccine contracts be delivered to the destination specified on the vaccine order within 15 working days after the contractor receives the order. NCIRD is notified by the contractor of all orders not shipped within the 15-day requirement. In general, the contractor receives the order within two days after the grantee submits the order to NCIRD through VACMAN.

(6) Price Revisions:

Vaccine contractors are provided an opportunity to revise unit prices twice during the one-year contract period, at four month intervals. At these preset dates (usually August 1 and December 1) each contractor may revise prices either upward or downward provided that the price per dose does not exceed the initial contract price. For instance, at the first price revision interval, contractors may only revise unit prices downward. At the second price revision interval, contractors may revise unit prices either upward or downward, provided the prices do not exceed the initial contract prices. Example: A contractor's initial award price for a vaccine is \$9.50 per dose. At the first price revision interval, the contractor revises the price to \$9.00 per dose. At the second price revision interval, the contractor could revise the price downward again or the contractor could revise the price upward but only to the initial award price of \$9.50 per dose.

C. Adult Vaccine Contracts

(1) Contract Period of Performance:

CDC adult vaccine contracts begin on July 1 of each year (or date of award if the contracts are awarded after July 1) and end on June 30 of the following year.

(2) Vaccines Covered:

A current listing of adult vaccines can be found online.

(3) Shelf Life:

Current CDC adult vaccine contracts indicate a specified shelf life that all vaccines must have remaining upon delivery by the manufacturer to the designated recipient (i.e., state depot or private distributor). This is usually, at least, 12 months.

(4) Vaccine Ordering:

The immunization programs may purchase vaccines from any of the available adult vaccine contracts using federal 317 grant funds or their own state/local funds. Federal VFC funds may NOT be used to purchase vaccine from CDC adult vaccine contracts because VFC funds are designated for the

purchase of vaccines for children from birth through 18 years of age.

Regardless of the funding source, immunization programs use VACMAN to order vaccine from the available contracts. Orders submitted through VACMAN are approved by NCIRD and forwarded to the vaccine contractors for fulfillment.

(5) Time of Delivery:

CDC's vaccine contracts stipulate that vaccines purchased from CDC's adult vaccine contracts be delivered to the destination specified on the vaccine order within 15 working days after the contractor receives the order. NCIRD is notified by the contractor of all orders not shipped within the 15-day requirement. In general, the contractor receives the order within two days after the grantee submits the order to NCIRD through VACMAN.

(6) Price Revisions:

Vaccine contractors are provided an opportunity to revise unit prices twice during the one-year contract period, at four month intervals. At these preset dates (usually November 1 and March 1) each contractor may revise prices either upward or downward provided that the price does not exceed the initial contract price. See price revision for consolidated pediatric/VFC vaccine contracts above as an example of price revision scenarios.

(7) Optional Use Provision:

CDC's adult vaccine contracts include an optional use clause which provides that county or local health departments and other publicly funded organizations may be authorized to purchase adult hepatitis A, adult hepatitis B and combination adult hepatitis A&B vaccines directly from the CDC contracts, if first approved by the immunization program and CDC. For further information on this provision see the Optional Use section of the appendix titled: Ordering Instructions – CDC Adult Vaccine Contracts.

D. Influenza Vaccine Contracts

(1) Contract Period of Performance:

CDC influenza vaccine contracts usually begin in the spring of the year (April or May) and end the following winter/spring (February or March).

(2) Vaccines Covered:

A current listing of influenza vaccines on CDC contracts can be found online.

(3) Shelf Life:

The trivalent inactivated influenza vaccines usually have an expiration date of June 30 (i.e. vaccines for use in the 2005-2006 influenza season would have an expiration date of June 30, 2006). The live attenuated influenza vaccine's expiration date is dependent on the date of production.

(4) Vaccine Ordering:

Immunization programs may purchase vaccines from any of the available contracts using federal VFC funds, federal 317 grant funds or their own state or local funds. Immunization programs use VACMAN to order vaccine from the available contracts. Orders submitted through VACMAN are approved by NCIRD and forwarded to the vaccine contractors.

(5) Time of Delivery:

Unlike other vaccines, influenza vaccines are not currently produced year round. Production is staged so that the vaccines are made available before or during the influenza season, although orders are pre-booked in late spring or early summer. Typically CDC influenza vaccine contracts stipulate that the contractors begin making partial shipments by no later than the end of September each year with remaining deliveries completed by the end of November.

(6) Price Revisions:

Price revisions are not allowed under CDC's influenza vaccine contracts.

ROLES & RESPONSIBILITIES

CDC's federal vaccine contracts are an important and integral part of the Vaccines for Children and 317 Grant programs. There are several parties with significant responsibilities in the acquisition and use of the federal vaccine contracts including the Procurement and Grants Office (PGO), the Financial Management Office (FMO), the National Center for Immunization and Respiratory Diseases (NCIRD), vaccine contractors (manufacturers or distributors), immunization programs, and providers using vaccine purchased from the federal contracts. The responsibilities of the various parties are outlined below:

NCIRD Responsibilities:

- (1) Initiates the vaccine acquisition process by developing and submitting a Request for Contract (RFC) to PGO. The RFC includes a list of vaccines, quantities required, a purchase description or Statement of Work (SOW), as applicable, and other supporting documentation
- (2) Evaluates vaccine contract proposals and makes recommendations for contract awards to PGO
- (3) Participates in contract negotiations with PGO and potential contractors
- (4) Initiates requests to PGO for modifications of contracts as necessary throughout the year
- (5) Processes immunization program vaccine orders which includes evaluating and approving and transmitting orders to the contractors for fulfillment
- (6) Maintains VACMAN and NIPVAC vaccine management and ordering systems
- (7) Works with FMO to ensure payment to manufacturers for vaccines within 30 days of grantee receipt
- (8) Works as liaison with immunization programs to resolve any vaccine order, vaccine shipment or vaccine cold chain issues
- (9) Allocates vaccine and helps to direct vaccine shipments when supplies are limited

PGO Responsibilities:

- (1) Issues/posts pre-solicitation notices and develops and posts the vaccine contract solicitations to the Federal Business Opportunities web site (www.fedbizopps.gov)
- (2) Receives vaccine contract proposals, coordinates the evaluation of proposals and leads negotiations with potential vaccine contractors
- (3) Awards and manages all CDC vaccine contracts
- (4) Administers and terminates contracts
- (5) Modifies vaccine contracts as necessary
- (6) Obligates federal funds
- (7) Assures vaccine contracts' adherence to Federal Acquisition Regulations (FAR)

FMO Responsibilities:

- (1) Processes and pays manufacturer vaccine invoices within 30 days of vaccine receipt
- (2) Verifies receipt of direct ship vaccines (varicella and FluMist) on a random basis by placing calls to various providers to verify receipt of vaccine (orders under \$25,000).

Vaccine Contractors' Responsibilities:

- (1) Informs CDC of any potential vaccine supply problems which may affect their ability to meet contract requirements
- (2) Delivers vaccine in accordance with contract terms and conditions (within 15 working days after receipt of order except influenza vaccine)
- (3) Provides CDC with invoices for payment of vaccines
- (4) Communicates to CDC through a weekly Delinquent Delivery Report any vaccine orders not delivered within 15 working days
- (5) Ships vaccine (with the exception of influenza vaccines) with the minimum shelf life specified in the contracts
- (6) Provides package inserts and Food and Drug Administration (FDA) required information

Immunization Programs' Responsibilities:

- (1) Transmits vaccine receipt information to CDC within 7 calendar days of receipt of a product purchased through CDC's federal vaccine contracts (see Figure 3 Vaccine Orders Flow). Grantees are required to submit their vaccine receiving information into VACMAN promptly, in order to avoid late fees incurred by CDC to the contractor
- (2) Completes ad-hoc surveys on anticipated vaccine usage (i.e., annual influenza estimates) as accurately as possible to help ensure the negotiated contract minimums and maximums for such vaccines are appropriate
- (3) Works with VFC providers to ensure they respond to FMO's delivery verification calls
- (4) Completes the Vaccine Ordering and Forecast Application (VOFA) annually
- (5) Places orders for vaccine and returns unused vaccine for excise tax credit

Provider Responsibilities:

- (1) Responds to FMO's delivery verification calls
- (2) Provides distributor with their medical license number, if needed, in order to receive direct-ship vaccines
- (3) Complies with state reporting requirements for public purchased vaccine received from the state immunization program

Figure 3 - Vaccine Orders Flow

FREQUENTLY ASKED QUESTIONS (FAQS)

- 1. Can entities such as private providers, insurance companies, Health Maintenance Organizations (HMO), and etc., purchase vaccines through the CDC contract?
 - No. Private providers cannot directly purchase vaccines through CDC contracts. In order to receive CDC purchased vaccines for eligible children, private providers must typically enroll in the VFC program in their state or locality.
- 2. Can states pool insurance funding and purchase vaccines through CDC's contracts for children not eligible for the VFC program?
 - The CDC vaccine contracts should not be used to purchase vaccines using private funds. This applies to all states, except those who were allowed to continue this practice at the beginning of the VFC Program. CDC believes that pooling of private funds to purchase vaccines could jeopardize the ability of CDC to obtain reduced price contracts. Federal vaccine contracts negotiated by the CDC provide substantial price discounts below the commercial prices available in the private market. Vaccine manufacturers participate voluntarily in this program. The system at present appears acceptable for the CDC to continue to receive price breaks. However, it is clear that to the extent there is a shift in the public/private shares through the establishment of private funding pools, such as a shift would likely have a significant impact on the potential for future public purchase at a discount.
- 3. Under what circumstances can non-grantees purchase adult hepatitis A and B vaccines through the CDC contract?
 - CDC vaccine contracts, including influenza contracts, are established for the purchase of vaccines by the immunization programs (the state health departments, certain large city immunization projects and certain current and former U.S. territories). Vaccines purchased from these contracts should be used for the programs' VFC and 317 grant populations and state eligible children and adults as applicable. The only current exception to this rule is for adult hepatitis A, adult hepatitis B and adult combination hepatitis A&B vaccines, which may be purchased by local agencies (for their employees) within the program's jurisdiction that have received written authorization from CDC to purchase directly from vaccine manufacturers for the CDC contracted price. These agencies must be publicly funded (receive a majority of their funding from public sources). For additional information on how agencies obtain authorization to purchase from CDC contractors, see appendix, Ordering Instructions CDC Adult Vaccine Contract.

4. Which vaccines can be purchased using 317 Financial Assistance (FA) funds?

Only vaccines such as PPV23 and other biologics such as immune globulin (IG) or hepatitis B immune globulin (HBIG), for which CDC does not have appropriate federal contracts, can be purchased with 317 FA funds.

5. Where do I find the current list of vaccines available through CDC contracts?

The <u>current price list</u> of vaccines available through CDC contracts can be found online.

6. Is it possible for a manufacturer to bid for a CDC vaccine contract when its vaccine has not been approved by the Food and Drug Administration?

No. Only manufacturers with a product license issued by the Food and Drug Administration (FDA) can bid on vaccine contracts for CDC's pediatric/VFC, adult and influenza contracts during a specified time indicated by a Request for Proposal. The contracts Request for Proposal (RFP) states that the vaccine "shall be manufactured under a current establishment and product license issued by the FDA" and that current good manufacturing practice regulations will be followed.

7. Why doesn't CDC have a VFC contract for pneumococcal polysaccharide vaccine?

The Omnibus Budget Reconciliation Act (OBRA) of 1993, which created the Vaccines for Children (VFC) program, also established price ceilings for covered vaccines, including pneumococcal polysaccharide vaccine. CDC is prohibited from making purchases with VFC funds at prices higher than the CDC contract prices in place as of May 1, 1993, adjusted for inflation. Since 1999 CDC has been unsuccessful in negotiating a VFC contract for this vaccine at a price no higher than the VFC ceiling price.

8. Why is there a delay between licensing of vaccines and their availability through the VFC program?

Although the procurement process begins shortly after a vaccine is licensed, a VFC contract for purchase of the vaccine is not established until a VFC resolution is approved for the VFC program by the Advisory Committee on Immunization
Practices (ACIP) and after publication of the ACIP's VFC resolution. VFC
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There are several elements for procuring vaccine contracts, as illustrated in Figure 4 below. Once NCIRD receives notification that a new vaccine has been licensed, a process begins for determining the necessary quantity and development of a request for contract (RFC). The RFC is the document that constitutes appropriate approval and authorization of an acquisition. The acquisition clock starts when a complete and workable RFC package is received at CDC's Procurement and Grants Office (PGO). Thus, there are many established CDC vaccine contract relationships (Figure 5) and several layers of review and coordination that must take place before the procurement process can begin.

PGO is responsible for securing a contract for the procurement of vaccine on behalf of NCIRD. The first step is the posting of a pre-solicitation announcement of the requirement on the Federal Business Opportunities web site.³ As required by the Small Business Act (15 U.S.C. 637(e)) and the Office of Federal Procurement Policy Act (41 U.S.C. 416), agencies must make notices of proposed contract actions available.⁴ Again, this site is the single government point-of-entry for federal government procurement opportunities over \$25,000. This announcement is posted for 15 calendar days. The primary purposes of the notice are to improve small business access to acquisition information and enhance competition by identifying contracting and subcontracting opportunities.⁵

Next, PGO posts a solicitation document or Request for Proposal (RFP) on the same web site. Vendors interested in receiving a contract must respond to PGO with a proposal by the established due date (usually within 30 days of solicitation posting). RFPs are used in negotiated acquisitions to communicate government requirements to prospective contractors and to solicit proposals. RFPs describe the—

- (1) Government's requirements;
- (2) Anticipated terms and conditions that will apply to the contract:
- (3) Information required to be in the offeror's proposal; and
- (4) Factors and significant subfactors that will be used to evaluate the proposal and their relative importance.

Upon receipt, proposals are reviewed and evaluated by PGO and NCIRD. Issues for discussion are developed and negotiations are then scheduled. Negotiations are usually conducted by conference call, and offerors then submit final proposal revisions, which are again evaluated by PGO and NCIRD. Contract documents are then prepared and transmitted for signature while the official contract file is undergoing a management review and approval process.

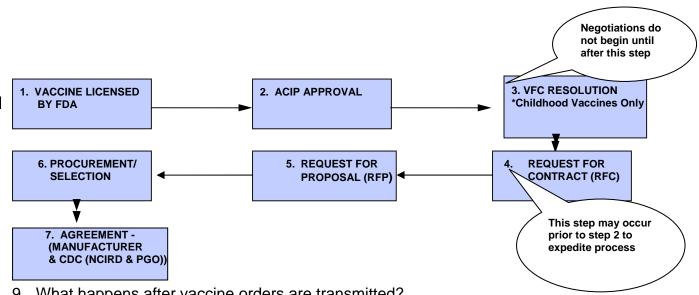
³ All CDC contract requirements that exceed \$25,000, unless exempt in accordance with FAR 5.202, must be posted online at http://fedbizopps.gov.

⁴ Federal Acquisitions Regulation - Subpart 5.2—Synopses of Proposed Contract Actions ⁵ Federal Acquisitions Regulation - Subpart 5.2—Synopses of Proposed Contract Actions

CDC routinely awards multiple contracts for vaccine products that are produced by more than one manufacturer.

ELEMENTS FOR PROCURING VACCINE CONTRACTS

Figure 4



9. What happens after vaccine orders are transmitted?

Once an immunization program transmits a vaccine order to CDC/NCIRD through VACMAN, orders are then transmitted and are received into the Vaccine Ordering System (NIPVAC) at CDC/NCIRD through a secure internet connection. Money is debited from a grantee's NIPVAC budget amount only after a favorable check against the grantee monthly allocation. NCIRD transmits the order to the contractor. The contractor or its distributor ships the order. Upon shipment of an order, the contractor sends an invoice to CDC/FMO. The status of the order is then transmitted to the immunization program through VACMAN, and, within 7 days of receipt of vaccine, the immunization program transmits receipt info to CDC/NCIRD. See ordering flow chart (figure 3).

10. How is contract size determined?

PGO and NCIRD negotiate contract maximum and minimum order size for each vaccine contract. NCIRD utilizes vaccine purchase projections submitted through VOFA, vaccine purchase information from recent CDC vaccine contracts, survey results from immunization programs, ACIP recommendations and population data in making a contract size determination.

- 11. Can VFC vaccine funds be used to purchase vaccines from the adult contracts?

 No.
- 12. Will vaccine contractors charge a service fee for any orders placed below the contract minimum doses ordered per shipping location?

Orders submitted through VACMAN for a quantity below the minimum order size will not be approved. Therefore, the issue of service fees does not apply.

There are many important relationships for successful CDC vaccine procurement. See below:

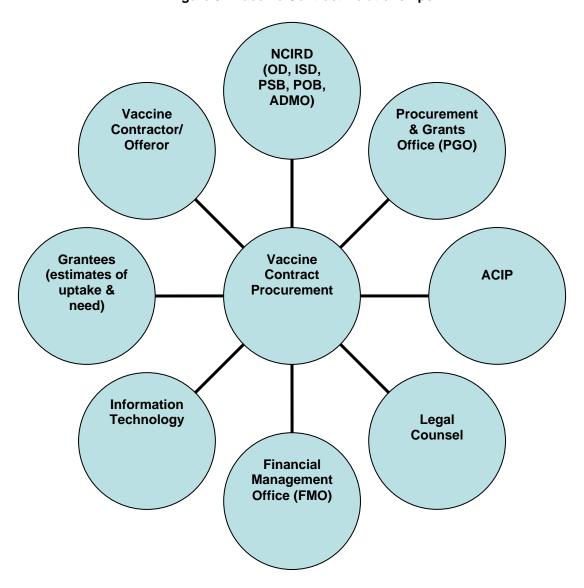


Figure 5 - Vaccine Contract Relationships

ACRONYMS

Advisory Committee on Immunization Practices (ACIP) - ACIP consists of 15 experts in fields associated with immunizations and infectious diseases who have been selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and CDC on the most effective means to prevent vaccine-preventable diseases. The Committee develops written recommendations for the routine administration of vaccines for the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. ACIP is the only entity in the federal government which makes such recommendations. The overall goals of the ACIP are to provide advice that assists the Department and the Nation in reducing the incidence of vaccine preventable diseases and to increase the safe usage of vaccines and related biological products. The ACIP meets three times each year and also determines which vaccines will be covered by the VFC program. These meetings are announced in notices published in the Federal Register and on NCIRD's website.

Associate Director of Management and Operations (ADMO) - Staff within CDC at the Center, Institute, Office and Division level that are responsible for all business related activities.

Centers for Disease Control & Prevention (CDC) — CDC is one of the major operating components of the Department of Health and Human Services (DHHS), which is the principal agency in the United States government for protecting the health and safety of all Americans and for providing essential human services, especially for those people who are least able to help themselves. With its headquarters and main laboratories in Atlanta, Georgia, CDC conducts research into the origin and occurrence of diseases and develops methods for their control and prevention. It also develops immunization services, together with state and local agencies; provides public health information; and aids in the training of health workers.

Centers for Medicare and Medicaid Services (CMS) – CMS administers the Medicare program and works in partnership with States to administer Medicaid, the State Health Insurance Program (SCHIP), and health insurance portability standards. CMS also evaluates quality standards in health care facilities and of providers through its survey and certification activity.

Department of Health and Human Services (DHHS) – DHHS is the United States government's principal agency for protecting the health of all Americans and providing essential human services. The Department's programs are administered by operating divisions, including eight agencies in the U.S. Public Health Service and three human

services agencies. They are the National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, Indian Health Service, Health Resources and Services Administration, Substance Abuse and Mental Health Services Administration, Agency for Healthcare Research and Quality, Centers for Medicare & Medicaid Services, Administration for Children and Families, Administration on Aging and the U.S. Public Health Service Commissioned Corps. DHHS administers more grant dollars than all other federal agencies combined.

Federal Acquisition Regulation (FAR) – The FAR is the primary regulation and document for use by all Federal Executive agencies in their acquisition of supplies and services, including vaccines, with appropriated funds. It became effective on April 1, 1984, and is issued within applicable laws under the joint authorities of the Administrator of General Services, the Secretary of Defense, and the Administrator for the National Aeronautics and Space Administration, under the broad policy guidelines of the Administrator, Office of Federal Procurement Policy, Office of Management and Budget.

Federally Qualified Health Center (FQHC) – FQHCs are private, non-profit or public organizations that receive federal grants from the Health Resources and Services Administration (HRSA) Bureau of Primary Health Care (BPHC) through Section 330 of the Public Health Service Act. The health centers' mission is to improve the health status of underserved populations. FQHCs (as well as Rural Health Clinics) are currently the only sites at which children who are underinsured with respect to vaccination are eligible to receive VFC vaccines.

Financial Management Office (FMO) – FMO, an office within CDC, provides the financial management of CDC's and the Agency for Toxic Substances and Disease Registry (ATSDR) annual appropriations. It is comprised of the Accounting Branch, Budget Branch, Financial Systems Branch, Financial Services Branch, and the Financial Policy and Internal Quality Assurance Activity.

Food and Drug Administration (FDA) – FDA is a consumer protection agency within the Department of Health and Human Services. The FDA promotes and protects the public's health by helping safe and effective products reach the market in a timely way, monitoring products for continued safety after they are in use, and helping the public get the accurate, science-based information needed to improve health. Vaccine product labeling/package insert information can be found at <u>FDA's Product Labeling web page</u>.

Health and Human Services Acquisition Regulations (HHSAR) – The HHSAR establishes uniform acquisition policies and procedures for the Department of Health and Human Services (DHHS) which conform to the Federal Acquisition Regulation (FAR) System. The HHSAR implements and supplements the FAR. (Implementing material expands upon or indicates the manner of compliance with related FAR material. Supplementing material is new material which has no counterpart in the FAR.) The HHSAR contains all formal departmental policies and procedures that govern the

acquisition process or otherwise control contracting relationships between the Department's contracting offices and contractors.

Health Resources and Services Administration (HRSA) - HRSA is the principal Federal Agency charged with increasing access to health care for those who are medically underserved.

Immunization Service Division (ISD) – ISD, a division within the National Center for Immunization and Respiratory Diseases at CDC, provides technical and administrative assistance to State and local health departments and other organizations in the implementation of immunization programs for the public and private sector. ISD has six branches: 1) Education, Information and Partnership Branch, 2) Health Services Research and Evaluation Branch, 3) Program Operations Branch, 4) Vaccine Supply and Assurance Branch, 5) Immunization Registry and Support Branch and 6) Assessment Branch.

Maternal and Child Health (MCH) – A branch of HRSA whose programs promote and improve the health of mothers, infants, children, and adolescents, including low-income families, those with diverse racial and ethnic heritages, and those living in rural or isolated areas without access to care.

National Center for Immunization and Respiratory Diseases (NCIRD) – NCIRD is the principal center at CDC that implements and monitors the federal immunization entitlement and grant programs. Formerly the National Immunization Program (NIP), NCIRD works to prevent disease, disability, and death in children and adults through vaccination and vaccination activities.

NIPVAC - NIPVAC is the back-end system that receives VACMAN provider and project vaccine orders. It provides the manufactures with vaccine order and shipping information, records vaccine order status, and returns that status into VACMAN. NIPVAC is also the primary source of VFC and 317 vaccine budget and purchase tracking.

Office of the Director (NCIRD/OD) – Manages and directs the activities of the National Center for Immunization and Respiratory Diseases (NCIRD); provides overall direction to, and coordination of, the scientific/medical programs of NCIRD; and provides leadership, coordination, and assessment of administrative management activities.

Omnibus Budget Reconciliation Act of 1993 (OBRA '93) – Section 13631 of the Omnibus Budget Reconciliation Act of 1993 created the Vaccines for Children (VFC) Program as a means of providing free vaccine to children aged 18 and younger who are uninsured, are eligible for Medicaid, or are Alaska Natives or American Indians. Underinsured children (those whose insurance does not cover childhood vaccinations) are also eligible for VFC vaccines, but may receive them only in federally qualified

health centers or rural health clinics. This entitlement program was signed into law on August 10, 1993. OBRA '93 is also known as Public Law 103-66.

Procurement and Grants Office (PGO) – PGO is the only entity within CDC that can obligate federal funds. PGO provides non-programmatic management for all CDC financial assistance activities (grants and cooperative agreements) and manages and awards all CDC contracts. PGO plays a vital role in furthering CDC's mission of promoting public health and improving the quality of life by preventing and controlling disease, injury, and disability. PGO's acquisition and assistance activities enable the centers, institutes and offices to implement health related programs, initiatives, or acquisitions. PGO also protects the public trust by ensuring the integrity, efficiency and effectiveness of the financial assistance and acquisition processes.

Program Operations Branch (POB) - Provides support to immunization grantees and local health departments in the form of technical and intervention assistance. This branch of ISD also monitors all infrastructure and vaccine funds awarded by CDC to immunization grantees.

Vaccine Supply and Assurance Branch (VSAB) – The Vaccine Supply and Assurance Branch make recommendations on all vaccine contracts, interact with vaccine manufacturers, and provides oversight and order placement for all vaccine purchases made through CDC's contracts. PSB works in a liaison capacity with other groups/programs representing the health interests of children, adolescents and adults including, but not limited to, ACIP, NVAC, FDA and vaccine manufacturers. Conducts or participates in operational research and demonstration projects, and training and educational activities on special initiatives. VSAB is also responsible for developing VFC resolutions and serves as subject matter experts on vaccine from pre-licensure through post evaluation.

Request for Contract (RFC) – The RFC is the formal document or acquisition plan which initiates the preparation of the solicitation by the contracting office and sets the acquisition process in motion. It is the result of the planning by the project officer and contracting officer and contains much of the pertinent information necessary for the development of a sound, comprehensive solicitation. To sum, this document constitutes appropriate approval and authorization of acquisition, allowing issuance of an RFP, and future obligation of funds, according to awarding component procedures.⁶

Request for Proposal (RFP) – A solicitation document used in negotiated acquisitions to communicate Government requirements to prospective contractors and to solicit proposals. The purpose of the RFP is to convey information that prospective offerors need to prepare a proposal. It describes all the information that prospective offerors must furnish to permit a meaningful and equitable evaluation of their offers. The RFP includes the Statement of Work (SOW), and the terms, conditions, and provisions that

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⁶ U.S. Department of Health and Human Services. DHHS Project Officers' Contracting Handbook

will form the basis for the final definitive contract. The RFP must be clear, complete, accurate, and consistent with the requirements of the acquisition so that it provides all who receive it with the same understanding of the requirements.⁷

Statement of Work (SOW) - The SOW is probably the single most critical document in the acquisition process. It defines requirements in clear, concise language identifying specific work to be accomplished. It also defines the respective responsibilities of the Government and the contractor, and provides an objective measure so that both the Government and the contractor will know when the work is complete and payment is justified.⁸

State Children's Health Insurance Program (SCHIP) – SCHIP is a capped entitlement or block grant program for States that was created by the *Balanced Budget Act of 1997*. SCHIP is financed jointly by the federal government and the States. Congress appropriated these funds to help States expand health insurance to children whose families earn too much to qualify for Medicaid, yet do not earn enough to afford private insurance.

Vaccine Injury Compensation Program (VICP) – The National Vaccine Injury Compensation Program (VICP) went into effect on October 1, 1988 and is a "no-fault" alternative to the traditional tort system for resolving certain vaccine injury claims. VICP has been a key component in stabilizing the U.S. vaccine market by providing liability protection to both vaccine companies and health care providers. Not only does it provide a more streamlined and less adversarial alternative to the traditional tort system for resolving claims, but also the VICP encourages research and development of new and safer vaccines. The VICP covers all vaccines recommended by CDC for routine administration to children. Vaccines for the following diseases are currently included: diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT, Td or Tdap), measles, mumps, rubella (MMR or any components), polio (OPV or IPV), hepatitis B, Haemophilus influenzae type b, varicella, rotavirus, pneumococcal disease, hepatitis A and influenza. VICP is administered jointly by the DHHS, and the Department of Justice (DOJ). The DHHS component of the VICP is located organizationally in HRSA, Division of Vaccine Injury Compensation (DVIC)). On March 24, 1997, a final rule was published, which provided for the "automatic" addition of future vaccines recommended by CDC for routine administration to children. However, Congress will still need to set an appropriate excise tax on any new vaccines recommended by CDC before those vaccines are effectively covered under the VICP.9

Vaccine Management Software (VACMAN) - VACMAN is a Database Management System used by 59 state, city, and territorial government immunization

(HRSA). About New Vaccines – Questions and Answers. http://www.hrsa.gov/vaccinecompensation/

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 U.S. Department of Health and Human Services - Health Resources and Services Administration

programs/projects. Only these projects, designated by CDC, are eligible to use VACMAN (the application is not designed for or accessible to any other agency or entity). The projects use VACMAN to order, and optionally to track and record information relating to VFC, 317 Grant and state/other funded vaccines.

Vaccine Ordering and Forecasting Application (VOFA) – VOFA is a software application designed to establish both the annual and monthly vaccine need for a grantee. The application is used to project funding needs for both the VFC and 317 vaccine purchase programs.

Vaccines for Children Program (VFC) – VFC is a federally funded program that provides vaccines for children from birth through 18 years of age who are uninsured, Medicaid eligible, Native Americans, or Alaska Natives at their doctors' offices. VFC also provides immunizations for children whose insurance does not cover immunizations at participating FQHCs and Rural Health Clinics (RHCs). The VFC program currently covers 29 different vaccines to prevent 15 diseases.

Vaccine Management Business Improvement Project (VMBIP) – VMBIP is a concerted effort by NCIRD to improve the basic operating system for vaccine ordering and distribution that will streamline vaccine management, accountability and business processes. The goals of the project are to improve 1) efficiency of vaccine ordering and delivery, 2) transparency of the vaccine supply chain, and 3) responsiveness to public health crises.

DEFINITIONS

317 Vaccine Funds – The 317 Grant program was established under section 317 of the Public Health Service Act. 10 Grants are provided to Immunization Programs for preventive health services. These grants are intended to help maintain immunization infrastructures or purchase vaccines not covered by private insurance or not available through the VFC program. These funds enable grantees to purchase vaccines and ensure that other basic functions of an immunization program are carried out. Section 317 funds require no matching of federal grants with state or local funds. The 317 program was intended to supplement state and local immunization efforts; grantees are specifically prohibited from using federal grant funds to replace existing state or local spending on immunization programs.

Contractor – One that agrees to furnish materials or perform services at a specified price and within a specified time frame.

Federal Excise Tax – A tax imposed on the production, sale, or consumption of a commodity such as vaccines. An excise tax of \$.75 (per antigen) on every dose of covered vaccine that is purchased is imposed upon the manufacturer of vaccines and revenues are placed into a fund to compensate those suffering complications of vaccination. It is also called a liability excise tax. In order for an excise tax to be imposed on a vaccine, excise tax legislation first must be approved by Congress.

Medicaid – Title XIX of the *Social Security Act* also known as Medicaid is a Federal/State entitlement program that pays for medical assistance for certain individuals and families with low incomes and resources. Enacted in 1965, Medicaid is a jointly funded program in which the Federal Government matches State spending to provide medical and health related services. Medicaid eligibility is limited to individuals who fall into specified categories. There are over 25 different eligibility categories for which Federal funds are available.

Medicare - Medicare is a sole federal social insurance program that entitles eligible persons to coverage for a defined set of benefits, including certain immunizations. All Medicare-eligible individuals enrolled in Part B of the program, whether entitled to coverage on the basis of age, disability, or coverage for end-stage renal disease (ESRD), are entitled to immunizations for influenza and pneumococcal disease, as well as for hepatitis B if determined to be at risk for that disease.

¹⁰ 42 U.S.C. sec. 247b.

Procurement – "Contract procurement" has the same meaning as "contract bidding." It is the process of securing contracts with vendors. This phase for vaccine contracts includes a request for contract (RFC) and request for proposal (RFP).

Project Officer – A project officer is assigned to each immunization program grantee. In addition to providing technical assistance, project officers for immunization program grantees serve as the primary point of contact for any CDC-related question and help link grantees with subject matter experts in a variety of areas related to immunization and vaccine-preventable diseases.

Vaccine Contract – A formal written agreement or purchase order, executed between the CDC and a vaccine supplier for the procurement of contractual vaccine services and commodities.

Vaccine Contracts Funding Sources – Vaccine contracts funding sources include VFC entitlement funds, 317 grant funds and State purchase funds. CDC supplies VFC vaccines and provides Section 317 vaccines and financial assistance awards to the states annually in response to state requests for assistance and estimates of vaccine need. Many states and some local governments contribute funds to the support of the national immunization system and are allowed to purchase vaccines through the established federal contracts.

Vaccine Manufacturer – An entity that produces/manufactures vaccines and vaccine related products.

VFC Resolution – A formal statement of a decision or expression of opinion put before and adopted by the Advisory Committee on Immunization Practices. VFC resolutions passed by the ACIP form the basis for VFC program policies on vaccine availability and usage. NCIRD and CMS communicate VFC resolutions to state immunization and Medicaid programs for dissemination to providers at the local level. VFC vaccine must be administered according to the guidelines outlined by the ACIP in the VFC resolutions.

RESOURCES

For additional information, see the following CDC websites.

Immunization Grant Program (Section 317) http://www.cdc.gov/programs/immun04.pdf

Influenza Immunization

http://www.cdc.gov/programs/immun06.pdf

Pediatric Vaccine Stockpiles

http://www.cdc.gov/programs/immun08.pdf

Vaccines For Children Program

http://www.cdc.gov/programs/immun10.pdf

CDC Vaccine Price List

http://www.cdc.gov/nip/vfc/cdc vac price list.htm

CDC Project Officer Assignments

http://www.cdc.gov/nip/vfc/contacts_proj-offic_regions.htm#progconsult

Vaccine Management System (VACMAN)

http://www.cdc.gov/nip/vacman/default.htm

ACIP: The VFC Resolutions Information Page

http://www.cdc.gov/nip/vfc/provider/acip whatis.htm#adding

ACIP VFC Resolutions (Printable Versions)

http://www.cdc.gov/nip/vfc/acip vfc resolutions.htm#res

NIP's Vaccine Excise Tax Credits Policy

http://www.cdc.gov/nip/vfc/st_immz_proj/forms/credit/nip_tax_policy.doc

Vaccine Storage and Handling Toolkit

http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html

Federal Business Opportunities

http://www.fedbizopps.gov/

National Vaccine Injury Compensation Program

http://www.hrsa.gov/vaccinecompensation/

National Vaccine Injury Compensation Program Fact Sheet

HRSA - National Vaccine Injury Compensation Program

ORDERING INSTRUCTIONS CDC Adult Vaccine Contracts Period: July 1, 2005 through June 30, 2006 Revision 2, December 6, 2005

Merck Vaccine Division

Contractor Contract No.

Merck Vaccine Division 200-2005-12567 P.O. Box 4

WP97B-358

West Point, PA 19486-00004

The following table lists the adult vaccine products and prices available from the Merck contract:

Item	Vaccine	Brand	NDC	Package	Price	Minimum
		Name	No.	Size	Per Dose	Order Size
0001	Hepatitis A	Vaqta ®	00006-	Pack of 1	\$18.50 *	30 Doses
	(Adult)		4841-00	Single Dose		
				Vial		
			00006-	Pack of 10	\$18.50 *	30 Doses
			4841-41	Single Dose		
				Vials		
0002	Hepatitis B	Recombivax-HB ®	00006-	Pack of 1	\$19.36 *	25 Doses
	(Adult)		4995-00	Single Dose		
				Vial		
			00006-	Pack of 10	\$21.23 *	25 Doses
			4995-41	Single Dose		
				Vials		
0003	Pneumococcal	Pneumovax ® 23	00006-	Pack of 10	\$14.00	100 Doses
	Polysaccharide		4739-50	5-Dose		
	(23 valent)			Vials		

^{*} Prices include \$0.75 per dose for Federal Excise Tax.

Ordering Address Remittance Address

Merck Vaccine Division Merck & Co., Inc. Order Management Center P.O. Box 7780-3061 P.O. Box 4, ZB 750

West Point, PA 19486

Philadelphia, PA 19182-3061

Page 2 - Ordering Instructions for CDC Adult Contracts - 7/1/05 - 6/30/06

GlaxoSmithKline

Contractor Contract No.
GlaxoSmithKline 200-2005-12645
Three Franklin Plaza (3F0625)
P.O. Box 13619
Philadelphia, PA 19101

The following table lists the vaccine products and prices available from the GlaxoSmithKline contract:

Item	Vaccine	Brand	NDC	Package	Price	Minimum
		Name	No.	Size	Per Dose	Order Size
0001	Hepatitis A	Havrix ®	58160-	Pack of 1 Single	\$18.50 *	30 Doses
	(Adult)		0835-01	Dose Vial		
			58160-	Pack of 5 Single	\$18.50 *	30 Doses
			0835-46	Dose Syringes		
				Without Needles		
0002	Hepatitis B	Engerix B®	58160-	Pack of 1 Single	\$24.25 *	25 Doses
	(Adult)		0857-01	Dose Vial		
			58160-	Pack of 5 Single	\$24.25 *	25 Doses
			0857-46	Dose Syringes		
				Without Needles		
0003	Hepatitis A&B	Twinrix ®	58160-	Pack of 10	\$36.91 **	30 Doses
	Combination		0850-11	1-Dose Vials		
	(Adult)					
			58160-	Pack of 5 Single	\$36.91 **	30 Doses
			0850-46	Dose Syringes		
				Without Needles		

^{*} Prices include \$0.75 per dose for Federal Excise Tax.

Ordering Address Remittance Address

GlaxoSmithKline GlaxoSmithKline Three Franklin Plaza, 3F0610 P.O. Box 740415

P.O. Box 13619 Atlanta, GA 30374-0415

Philadelphia, PA 19101

^{**} Prices include \$1.50 per dose for Federal Excise Tax.

Page 3 - Ordering Instructions for CDC Adult Contracts - 7/1/05 - 6/30/06

Henry Schein Inc.

<u>Contract No.</u>

Henry Schein Inc. 200-2005-12632

135 Duryea Road Melville, NY 11747

The following table lists the adult vaccine products and prices available from the Henry Schein Inc. contract:

Item	Vaccine	Brand	NDC	Package	Price	Minimum
		Name	No.	Size	Per Dose	Order Size
0001	Tetanus and	Tetanus and	14362-	Pack of 1	\$9.75 **	60 Doses
	Diphtheria	Diphtheria	0111-1	15-Dose		
	Toxoids *	Toxoids		Vials		
		Adsorbed for				
		Adults				

^{*} Henry Schein Inc. is supplying Td vaccine manufactured by Massachusetts Biologic Laboratories.

Ordering Address Remittance Address

Henry Schein, Inc.
Henry Schein, Inc.
135 Duryea Road
Melville, NY 11747
Henry Schein, Inc.
135 Duryea Road
Melville, NY 11747

^{**} Prices include \$1.50 per dose for Federal Excise Tax.

Page 4 - Ordering Instructions for CDC Adult Contracts -7/1/05 - 6/30/06The following information is applicable to all of the above listed contracts:

PAYMENT DISCOUNT RETURN PRIVILEGES

Net 30 None

TIME OF DELIVERY PACKAGING/PACKING

Within 15 days Standard Commercial Manner

from date of order

METHOD OF PAYMENT:

Payment for orders utilizing Federal, State, or local funds will be made not later than 30 days after receipt of an invoice by the ordering office. You are further advised that the Prompt Payment Act, Public Law 97-177 (96 Stat. 85, 31 USC 1801) is applicable to payments under this contract and requires payment of interest on overdue payments and improperly taken discounts. Upon receipt and acceptance of partial deliveries, payment shall be made in accordance with the provision stated above.

INSPECTION/ACCEPTANCE:

Inspection/acceptance required by this contract will be completed no later than three working days after receipt of vaccine.

OPTIONAL USE:

Immunization projects (grantees) may place orders against these contracts using federal 317 grant funds and/or state funds. In addition, county or local health departments and other publicly funded organizations may be authorized to purchase adult Hepatitis A, adult Hepatitis B and combination adult Hepatitis A&B vaccines directly from the CDC contracts, if first approved by the immunization project. These organizations should submit a letter to their immunization project requesting that they be authorized to purchase these adult Hepatitis vaccines from the CDC contracts. The letter should include the certification form attached hereto as Attachment 1, or similar form. If the immunization project approves the organization's request, the request should then be submitted to Ms. Beth West at the Centers for Disease Control and Prevention's Procurement and Grants Office (PGO) either by E-mail or fax. Beth's E-mail address is BWest@cdc.gov and her fax number is 770-488-2777 (a fax cover sheet to the attention of Beth West should accompany any fax transmission). Organizations which have been previously approved to purchase hepatitis B vaccine do not need to resubmit. NOTE: This extended Toxoid vaccines.

Page 5 - Ordering Instructions for CDC Adult Contracts - 7/1/05 - 6/30/06

OTHER:

- a. All vaccine will be ordered or confirmed by written purchase orders, each citing as a minimum the following:
 - (1) Date of Order
 - (2) Contract Number and Order Number
 - (3) Item Description, Quantity and Unit Price
 - (4) Delivery or Performance Date
 - (5) Place of Delivery or Performance (Including Consignee)
 - (6) Packaging, Packing, and Shipping Instructions, If Any
 - (7) Accounting and Appropriation Data
 - (8) Statement to indicate if partial deliveries are not acceptable (Lack of a statement shall be construed to mean partial deliveries are acceptable and payment shall be made as required elsewhere herein)
 - (9) Any Other Pertinent Data
- b. Orders may be issued against this contract up to and including the last day of the contract period, provided delivery is called for within delivery period specified in the contract.

RESTRICTIONS ON USE OF VACCINES OBTAINED BY GRANTEES

All vaccines obtained under Federal procurement contracts must be used solely for purposes of Federal immunization programs. Sale of such vaccines to any person or entity is strictly prohibited. Free distribution of such vaccines is also prohibited, except where such vaccines are administered in the context of Federal immunization program activities.

A COPY OF ALL PURCHASE ORDERS ISSUED UNDER THE CONTRACT SHALL BE FORWARDED TO:

Centers for Disease Control & Prevention (CDC) National Immunization Program Mailstop E-52 1600 Clifton Road, N.E. Atlanta, Georgia 30333

PRICE REVISIONS:

Each of these contracts includes a provision for the revision of unit prices at the option of the Contractors. Effective dates for the price revisions, if applicable, shall be as follows: November 1, 2005 and March 1, 2006. CDC will advise of any such price revisions.

AGREEMENT FOR THE PURCHASE OF ADULT HEPATITIS VACCINES FROM THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) ADULT VACCINE CONTRACT(S)

As a condition for purchasing adult Hepatitis A, adu	It Hepatitis B and/or adult
combination Hepatitis A&B vaccines from the CDC	Adult Vaccine Contract(s),

I/V			
	(Print N	Name/Address of Agency/Hospital/Clinic	
ag	ree to the f	following conditions:	
1.	CDC Adulting statement Injury Act,	fy that in administering the adult Hepatitis valt Vaccine Contract(s), I will provide each pasuch vaccine a copy of the currently approvet" or, for any of the vaccines covered by the the appropriate "Vaccine Information States ation of each dose of such vaccine.	tient (parent or guardian) ed "Important Information National Childhood Vaccine
2.	of 10 year administer appropriat	etain the signature portion containing the recess following the end of the calendar year in we red and, upon request, furnish copies of the te health department or the Centers for Disecent of Health and Human Services.	which the vaccine is required information to an
3.		e will be made to any patient for vaccine pure ted contract(s).	chased from the federal
4.		e to pay all appropriate charges for vaccine eceipt of an invoice for the order.	no later than 30 calendar days
5.		abide by the conditions of the contract(s) wi	
			Date:
(S	Signature of	f Person Authorized to Sign for Facility)	
(F	Print Name	and Title)	

ORDERING INSTRUCTIONS

Consolidated Pediatric/Vaccines For Children (VFC) Contracts Period: April 1, 2005 through March 31, 2006 Revision 3, December 14, 2005

The Centers for Disease Control & Prevention (CDC) has awarded the four contracts listed below for the purchase of vaccines covered under the Vaccines For Children program for the period April 1, 2005 through March 31, 2006. Specific information concerning the vaccines awarded under each of the contracts is provided on the pages listed below. Authorized purchasers may order vaccine from any or all of these contracts.

Contract Number	Contractor	Page Numbers
200-2005-11531	sanofi pasteur Inc.	2 - 5
200-2005-11532	GlaxoSmithKline	6 - 9
200-2005-11533	Merck Vaccine Division	10 - 13
200-2005-11534	Wyeth Pharmaceuticals	14

Page 2 – Ordering Instructions for CDC's 2005 Pediatric/VFC Vaccine Contracts

sanofi pasteur Inc.

<u>Contract No.</u>

sanofi pasteur Inc. 200-2005-11531

Discovery Drive Swiftwater, PA 18370

Contract Line

<u>Item No. (CLIN)</u> <u>Vaccine Description</u>

0001(a) Diphtheria and Tetanus Toxoid with Acellular Pertussis (DTaP)

Product/Brand Name: Tripedia ®

Minimum Order Size: 100 Doses Per Destination

Description NDC Number Unit Price Price Per Dose DTaP Vaccine 49281-298-10 \$100.00 \$10.00 Packages of 10 Single Dose Vials Fed. Excise Tax \$ 22.50 \$ <u>2.25</u> Total \$122.50 \$12.25

Contract Line

Item No. (CLIN) Vaccine Description

0001(b) Diphtheria and Tetanus Toxoid with Acellular Pertussis (DTaP)

Product/Brand Name: DAPTACELTM

Minimum Order Size: 100 Doses Per Destination

Description NDC Number Unit Price Price Per Dose DTaP Vaccine 49281-286-10 \$105.00 \$10.50 Packages of 5 Single Dose Vials Fed. Excise Tax \$ 22.50 \$ <u>2.25</u> \$127.50 \$12.75 Total

Page 3 – Ordering Instructions for CDC's 2005 Pediatric/VFC Vaccine Contracts (sanofi - Contract No. 200-2005-11531 - Continued)

Contract Line

Item No. (CLIN) Vaccine Description

0002 Diphtheria and Tetanus Toxoid with Acellular Pertussis

Vaccine Combined with Haemophilus Influenza b (DTaP/Hib)

Product/Brand Name: TriHIBit ®

Minimum Order Size: 100 Doses Per Destination

<u>Description</u>	NDC Number	<u>Unit Price</u>	Price Per Dose
DTaP/Hib Vaccine Packages of 5 Single Dose Vials	49281-597-05	\$108.10	\$21.62
	Fed. Excise Tax Total	\$\frac{15.00}{\$123.10}\$\$ \$\frac{3.00}{\$24.62}\$\$	

Contract Line

Item No. (CLIN) Vaccine Description

Enhanced Inactivated Poliovirus Vaccine (E-IPV)

Product/Brand Name: IPOL ®

Minimum Order Size: 1,000 Doses Per Destination

Description	NDC Number	<u>Unit Price</u>	Price Per Dose
E-IPV Vaccine 10 Dose Vials	49281-860-10	\$ 96.70	\$ 9.67
	Fed. Excise Tax Total		0.7 <u>5</u> 0.42

Page 4 – Ordering Instructions for CDC's 2005 Pediatric/VFC Vaccine Contracts (sanofi - Contract No. 200-2005-11531 - Continued)

Contract Line

Item No. (CLIN) Vaccine Description

0004 Haemophilus Influenza Type b Vaccine (Hib)

Product/Brand Name: ActHIB®

Minimum Order Size: 800 Doses Per Destination

<u>Description</u>	NDC Number	<u>Unit Price</u>	Price Per Dose
Hib Vaccine Package of 5 Single Dose Vials	49281-545-05	\$34.57	\$6.914
-	Fed. Excise Tax Total	\$ <u>3.75</u> \$38.32	\$ <u>0.75</u> \$7.664

Note: This vaccine is a 4-dose series.

Contract Line

<u>Item No. (CLIN)</u> <u>Vaccine Description</u>

0005 Tetanus and Diphtheria Toxoids Vaccine (Td)

Product/Brand Name: DECAVAX TM

Minimum Order Size: 100 Doses Per Destination

<u>Description</u>	NDC Number	<u>Unit Price</u>	<u>Price Per Dose</u>
Td Vaccine Package of 10 Single Dose 0.5ml Syringes	49281-291-10	\$144.00	\$14.40
•	Fed. Excise Tax Total	\$ <u>15.00</u> \$159.00	\$ <u>1.50</u> \$15.90

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Contract Line

<u>Item No. (CLIN)</u> <u>Vaccine Description</u>

0006 Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (MCV4)

Product/Brand Name: MENACTRA ® Minimum Order Size: 10 Doses Per Destination

Description	NDC Number	<u>Unit Price</u>	<u>Price Per Dose</u>
MCV4 Vaccine Single Dose Vials	49281-589-01	\$68.00	\$68.00
MCV4 Vaccine	49281-589-05	\$340.00	\$68.00

Package of 5 Single Dose Vials

Contract Line

<u>Item No. (CLIN)</u> <u>Vaccine Description</u>

0007 Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)

Product/Brand Name: ADACEL TM

Minimum Order Size: 50 Doses Per Destination

Description	NDC Number	Unit Pr	rice	Price Per Dose
Tdap Vaccine Package of 10 Single Dose Vials	49281-400-10	\$285.0	0	\$28.50
Single Bose Viais	Fed. Excise Tax	\$ <u>22.50</u>	\$ <u>2.25</u>	
	Total	\$307.50	\$30.75	

Ordering Address Remittance Address

sanofi pasteur Inc. sanofi pasteur Inc.

Discovery Drive 12458 Collections Center Drive

Swiftwater, PA 18370-0187 Chicago, IL 60693

Page 6 – Ordering Instructions for CDC's 2005 Pediatric/VFC Vaccine Contracts GlaxoSmithKline

<u>Contract No.</u>

GlaxoSmithKline 200-2005-11532

Three Franklin Plaza (3F0625) P.O. Box 13619 Philadelphia, PA 19101

Contract Line

<u>Item No. (CLIN)</u> <u>Vaccine Description</u>

0001 Diphtheria and Tetanus Toxoid with Acellular Pertussis (DTaP)

Product/Brand Name: INFANRIX ®

Minimum Order Size: 100 Doses Per Destination

<u>Description</u>	<u>NDC #</u>	<u>Unit Price</u>	Price Per dose
DTaP Pkg. of 10 1-dose Vials	58160-0840-11	\$105.00	\$10.50
	Fed. Excise Tax Total	\$\frac{22.50}{\$127.50} \ \\$\frac{2.25}{\$12.75}	
DTaP Pkg. of 5 single-dose prefilled syringes	58160-0840-46	\$ 52.50	\$10.50
	Fed. Excise Tax	\$ <u>11.25</u> \$ <u>2.25</u>	
	Total	\$ 63.75 \$12.75	
Contract Line			
Item No. (CLIN)	Vaccine Description		

0002

Diphtheria and Tetanus Toxoids with Acelullar Pertussis Abosrbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined (DTaP/Hepatitis B/IPV)

Product/Brand Name: PEDIARIX ®

Minimum Order Size: 100 Doses Per Destination

<u>Description</u>	NDC #	<u>Unit Price</u>	Price Per dose
DTaP/Hep B/IPV Pkg. of 10 Single dose Vials	58160-0841-11	\$345.90	\$34.59
	Federal Excise Tax Total	\$ <u>37.50</u> \$383.40	\$ <u>3.75</u> \$38.34

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(GlaxoSmithKline - Contract No. 200-2005-11532 - Continued)

<u>Description</u>	NDC #	<u>Unit Price</u>	Price Per Dose
DTaP/Hep B/IPV Pkg. of 5 Single dose Syringes	58160-0841-46	\$172.95	\$34.59
	Fed. Excise Tax Total		3.75 38.34

Contract Line

Item No. (CLIN) Vaccine Description

0003 Hepatitis A Pediatric Vaccine

Product/Brand Name: HAVRIX ®

Minimum Order Size: 10 Doses Per Destination

<u>Description</u>	NDC #	<u>Unit Pri</u>	<u>ce</u>	<u>Price Per Dose</u>
Hepatitis A Pediatric Single dose vials	58160-0837-01	\$11.35		\$11.35
	Fed. Excise Tax Total	\$ <u>0.75</u> \$12.10	\$ <u>0.75</u> \$12.10	
Pkg. of 10 1-dose via	ls 58160-0837-11	\$113.50		\$11.35
	Fed. Excise Tax Total	\$ <u>7.50</u> \$121.00	\$ <u>0.75</u> \$12.10	
Pkg. of 5 Single dose syringes	58160-0837-46	\$56.75		\$11.35
, ,	Fed. Excise Tax Total	\$ <u>3.75</u> \$60.50	\$ <u>0.75</u> \$12.10	

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(GlaxoSmithKline - Contract No. 200-2005-11532 - Continued)

Contract Line

Item No. (CLIN) Vaccine Description

0004 Combination Hepatitis A and Hepatitis B Adult Vaccine (For Age

18 only)

Product/Brand Name: TWINRIX ® Combined Hepatitis A and B Vaccine

Minimum Order Size: 10 Doses Per Destination

<u>Description</u>	NDC #	<u>Unit Price</u>	Price Per Dose
Combination Hep A/B Adult	58160-0850-11	\$354.10	\$35.41
Package of 10 Single dose vials	Fed. Excise Tax Total	\$ <u>15.00</u> \$369.10	\$ <u>1.50</u> \$36.91
Combination Hep A/B Adult	58160-0850-46	\$177.05	\$35.41
Package of 5 Single-dose syringes	Fed. Excise Tax Total	\$ <u>7.50</u> \$ <u>1</u> \$184.55	<u>.50</u> \$36.91

Contract Line

Item No. (CLIN) Vaccine Description

0005 Hepatitis B Pediatric/Adolescent Vaccine (Ages 0-18)

Product/Brand Name: Engerix-B ®

Minimum Order Size: 25 Doses Per Destination

<u>Description</u>	NDC #	<u>Unit Pr</u>	<u>ice</u>	<u>Price Per Dose</u>
Hepatitis B Ped/Adol Single dose vials	58160-0856-01	\$8.25		\$8.25
C	Fed. Excise Tax Total	\$ <u>0.75</u> \$9.00	\$ <u>0.75</u> \$9.00	
Pkg. of 10 Single dose vials	58160-0856-11	\$82.50		\$8.25
	Fed. Excise Tax Total	\$ <u>7.50</u> \$90.00	\$ <u>0.75</u> \$9.00	

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(GlaxoSmithKline - Contract No. 200-2005-11532 - Continued)

<u>Description</u>	<u>NDC #</u>	Unit Price	<u>Price Per Dose</u>
Hepatitis B Ped/Adol Pkg. of 5 Single Dose Syringes	58160-0856-46	\$41.25	\$8.25
	Fed. Excise Tax Total	\$\frac{3.75}{\$45.00}\$\$ \$\frac{9.75}{\$9.0}\$\$	

Contract Line

<u>Item No. (CLIN)</u> <u>Vaccine Description</u>

Minimum Order Size: 10 Doses Per Destination

0006 Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)

Product/Brand Name: BOOSTRIX TM

<u>Description</u>	NDC Number	<u>Unit Pri</u>	<u>ce</u>	Price Per Dose
Tdap Vaccine Package of 10 Single Dose Vials	58160-0842-11	\$265.00		\$26.50
	Fed. Excise Tax Total	\$ <u>22.50</u> \$287.50	\$ <u>2.25</u> \$28.75	
Pkg. of 5 Single-dose Syringes	58160-0842-46	\$132.50)	\$26.50
	Fed. Excise Tax	\$ <u>11.25</u>	\$ <u>2.25</u>	

Ordering Address Remittance Address

Total

GlaxoSmithKline Gla:
Three Franklin Plaza (3F0610) P.O.
P.O. Box 13619 Atla
Philadelphia, PA 19101

GlaxoSmithKline P.O. Box 740415 Atlanta, GA 30374-0415

\$143.75

\$28.75

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Merck Vaccine Division

<u>Contract No.</u>

Merck Vaccine Division 200-2005-11533

P.O. Box 4, WP97-B-358 Sumneytown Pike West Point, PA 19486

Contract Line

Item No. (CLIN) Vaccine Description

0001 Hepatitis A Pediatric Vaccine

Product/Brand Name: VAQTA ®

Minimum Order Size: 100 Doses Per Destination

<u>Description</u> <u>NDC #</u> <u>Unit Price</u> <u>Price Per Dose</u>

Hepatitis A Pediatric 0006-4831-41 \$114.00 \$11.35

Package of 10

Single dose vials

Fed. Excise Tax \$ <u>7.50</u> \$ <u>0.75</u> Total \$121.50 \$12.10

Contract Line

Item No. (CLIN) Vaccine Description

0002 Hepatitis B Pediatric/Adolescent Vaccine (Ages 0-18)

Product/Brand Name: Recombivax HB^R Thimerosal Free/Preservative Free

00006-4981-00

Minimum Order Size: 100 Doses Per Destination

<u>Description</u> <u>NDC #</u> <u>Unit Price</u> <u>Price Per Dose</u>

Hepatitis B Vaccine Package of 10

Single dose vials

Fed. Excise Tax \$\frac{7.50}{50.00}\$ \$\frac{90.75}{9.00}\$

\$82.50

\$8.25

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(Merck - Contract No. 200-2005-11533 - Continued)

Contract Line

Item No. (CLIN) Vaccine Description

0003 Hepatitis B Vaccine (2-dose Regimen) for Adolescents Age 11-15

Product/Brand Name: Recombivax HB®

Minimum Order Size: 50 Doses Per Destination

<u>Description</u> NDC # Unit Price Per Dose

Hepatitis B Vaccine 00006-4995-41 \$235.00 \$23.50

(2-Dose) Pkg. of 10 Single dose vials

> Fed. Excise Tax \$ <u>7.50</u> \$ <u>0.75</u> Total \$242.50 \$24.25

Contract Line

<u>Item No. (CLIN)</u> <u>Vaccine Description</u>

0004 Hepatitis B Vaccine combined with Haemophilus Influenza Type

b (Hep B/Hib)

Product/Brand Name: Comvax ®

Minimum Order Size: 100 Doses Per Destination

<u>Description</u> <u>NDC #</u> <u>Unit Price</u> <u>Price Per Dose</u>

Hepatitis B/Hib 0006-4898-00 \$230.00 \$23.00

Pkg. of 10

Single dose vials

Fed. Excise Tax \$ <u>15.00</u> \$ <u>1.50</u> Total \$245.00 \$24.50

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(Merck - Contract No. 200-2005-11533 - Continued)

Contract Line

<u>Item No. (CLIN)</u> <u>Vaccine Description</u>

0005 Haemophilus Influenza Type b (Hib)

Product/Brand Name: Pedvax HIB ®

Minimum Order Size: 800 Doses Per Destination

Description NDC # Unit Price Per Dose

Hepatitis B/Hib 0006-4897-00 \$ 94.70 \$ 9.47

Pkg. of 10

Single dose vials

Fed. Excise Tax \$ 7.50 \$ 0.75 Total \$102.20 \$10.22

Contract Line

Item No. (CLIN) Vaccine Description

0006 Measles, Mumps and Rubella Combination Vaccine

Product/Brand Name: M-M-R II ®

Minimum Order Size: 400 Doses Per Destination

Description NDC# Unit Price Price Per Dose 0006-4681-00 MMR Vaccine \$144.20 \$14.42 Pkg. of 10 Single dose vials Fed. Excise Tax \$ 22.50 \$ 2.25 Total \$166.70 \$16.67

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(Merck - Contract No. 200-2005-11533 - Continued)

Contract Line

Item No. (CLIN) Vaccine Description

0007 Varicella Vaccine

Product/Brand Name: Varivax ®

Minimum Order Size: 10 Doses Per Destination

DescriptionNDC #Unit PricePrice Per DoseVaricella0006-4827-00\$515.00\$51.50Pkg. of 10Single dose vialsFed. Excise Tax\$ 7.50\$ 0.75

Fed. Excise Tax \$ \frac{7.50}{522.50} \$ \frac{0.75}{522.50}\$

Ordering Address Remittance Address

Merck Vaccine Division Merck & Co., Inc. P.O. Box 4, ZB-750 P.O. Box 7780-3061

West Point, PA 19486 Philadelphia, PA 19182-3061

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Wyeth Pharmaceuticals

Contract No.

Wyeth Pharmaceuticals 200-2005-11534

33 Morehall Road Frazer, PA 19355

Contract Line

Item No. (CLIN) Vaccine Description

O002 Pneumococcal Conjugate Pediatric Vaccine (7 Valent)

Product/Brand Name: Prevnar ®

Minimum Order Size: 200 Doses Per Destination

Unit Price <u>Description</u> NDC# Price Per Dose Pneu. Conjugate 0005-1970-67 \$266.85 \$53.37 Pkg. of 5 Single dose vials Fed. Excise Tax \$<u>3.75</u> \$ 0.75 \$270.60 \$54.12 Total

Ordering Address Remittance Address

Wyeth Pharmaceuticals W8175

Central Customer Service Unit Wyeth Pharmaceuticals

P.O. Box 1773 P.O. Box 7777

Paoli, PA 19301-1773 Philadelphia, PA 19175-8175

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The following information is applicable to all of the above listed contracts:

<u>PAYMENT DISCOUNT</u> <u>RETURN PRIVILEGES</u>

Net 30 None

TIME OF DELIVERY PACKAGING/PACKING

Within 15 days Standard Commercial Manner

from date of order

METHOD OF PAYMENT:

Payment for orders utilizing Federal, State, or local funds will be made not later than 30 days after receipt of an invoice by the ordering office. You are further advised that the Prompt Payment Act, Public Law 97-177 (96 Stat. 85, 31 USC 1801) is applicable to payments under this contract and requires payment of interest on overdue payments and improperly taken discounts. Upon receipt and acceptance of partial deliveries, payment shall be made in accordance with the provision stated above.

INSPECTION/ACCEPTANCE:

Inspection/acceptance required by this contract will be completed no later than three working days after receipt of vaccine.

PURCHASES BY AUTHORIZED USERS:

Authorized users may place orders against this contract using Federal or State and local funds. The Contractor shall honor all authorized optional funding orders from these agencies.

OTHER:

- a. All vaccine will be ordered or confirmed by written purchase orders, each citing as a minimum the following:
 - (1) Date of Order
 - (2) Contract Number and Order Number
 - (3) Item Description, Quantity and Unit Price
 - (4) Delivery or Performance Date
 - (5) Place of Delivery or Performance (Including Consignee)
 - (6) Packaging, Packing, and Shipping Instructions, If Any
 - (7) Accounting and Appropriation Data
 - (8) Statement to indicate if partial deliveries are not acceptable (Lack of a statement shall be construed to mean partial deliveries are acceptable and payment shall be made as required elsewhere herein)
 - (9) Any Other Pertinent Data

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The following information is applicable to all of the above listed contracts:

b. Orders may be issued against this contract up to and including the last day of the contract period, provided delivery is called for within delivery period specified in the contract.

RESTRICTIONS ON USE OF VACCINES OBTAINED BY GRANTEES

All vaccines obtained under Federal procurement contracts must be used solely for purposes of Federal immunization programs. Sale of such vaccines to any person or entity is strictly prohibited. Free distribution of such vaccines is also prohibited, except where such vaccines are administered in the context of Federal immunization program activities.

A COPY OF ALL PURCHASE ORDERS ISSUED UNDER THE CONTRACT SHALL BE FORWARDED TO:

Centers for Disease Control & Prevention (CDC) National Immunization Program Mailstop E-52 1600 Clifton Road, N.E. Atlanta, Georgia 30333

PRICE REVISIONS:

Each of these contracts includes a provision for the revision of unit prices at the option of the Contractors. Effective dates for the price revisions, if applicable, shall be as follows: August 1, 2005 and December 1, 2005. CDC will advise of any such price revisions.